

REMARKS

Claims 1-24 are currently pending in the present application. Claims 1, 14, and 24 are independent claims. Claim 1 is drawn to an encapsulated product comprising at least one active ingredient, at least one compressible material, and at least one lubricating material with the product being in the form of a caplet of diameter and length of about 1-7 millimeters. Claims 2-13 are dependent from claim 1 and add further limitations. Claim 14 is drawn to a method for preparing an encapsulated product comprising the steps of blending an active ingredient with a compressible material, mixing the compressible material with a lubricating material to form a final mixture, compressing the final mixture into a caplet having a diameter and length of about 1-7 millimeters. Claims 15-23 are dependent from claim 14 and add further limitations. Claim 24 is drawn to a method of delivering two flavor ingredients to an item selected from the group consisting of a food item, a confectionery product, and a chewing gum product with the method comprising incorporating into the item a first encapsulated product containing a first flavor and incorporating into the item a second encapsulated product containing a second flavor.

Claims 2, 9, 11 and 19, 20, 22 and 24 are rejected under 35

U.S.C. §112, second paragraph as being indefinite. By this Amendment, claims 2, 9, 11 and 19, 20 and 24 are amended, thus overcoming the 35 U.S.C. §112, second paragraph rejection. No new matter within the meaning of 35 USC § 132 has been added. Also, claims 1-14, 19-23 are rejected under 35 U.S.C. §103(a) as being unpatentable over Fielden. Claim 24 is rejected under 35 U.S.C. §103(a) as being unpatentable over Cherukuri et al.

Applicant thanks the Examiner for the indication that claims 15-18 would be allowable if rewritten in independent form including all the limitations of the base claim and any intervening claims.

The claim amendments are presented in the expectation that the amendments will place this application in condition for allowance. Accordingly, entry of the amendments is respectfully requested.

**1. REJECTION OF CLAIMS 2, 9, 11 and 19, 20, 22
UNDER 35 U.S.C. §112, SECOND PARAGRAPH**

Claim 2, 9, 11 and 19, 20, 22 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite. As a basis for this rejection, the Office Action states:

Claim 2 and 19 are indefinite in the use of the ingredients in the group consisting of and non-herbal ingredients. All of the ingredients in the group are food additives, which is one of the items in the group. Also, it is not known what

is meant by the phrase non-herbal ingredients. Claim 9 is indefinite in the use of the phrase said compressible material is selected from the groups of sugar, fiber, polyols and mineral salts consisting of ... and mixtures thereof. Claim 20 has the same problem. The cited phrase is not understood. Also, in claims 9 and 20, there is no specific listing of the type of fiber required. In claims 11 and 22 in the Markush grouping from the group consisting of fats...waxes. Waxes are considered to be part of the wide group of fats. Therefore, the use of the term fat overlaps with the term wax and using both terms is considered to be redundant. Claim 24 is indefinite in the use of the phrases a food item, and a confectionary product. Confectionary products are considered to be foods, therefore the phrases overlap and are redundant.

RESPONSE

Applicant respectfully traverses the rejection of claims 2 and 19 because they do not incorporate the claim limitations, "ingredients" and "non-herbal ingredients". The base claims for claims 2 and 19 are claims 1 and 14, respectively which do not contain these limitations.

Applicant also traverses the rejection as to claims 2 and 19 because food additives and non-herbal ingredients particularly point out and distinctly claim the subject matter of the invention. However, Applicant has deleted "food additives" and "non-herbal ingredients" from claims 2 and 19, thereby removing the basis of the rejection.

Applicant has amended claims 9 and 20, thus rendering the rejection of those claims moot.

Applicant also traverses the rejection as to claims 11 and 22 because waxes are not considered to be part of the wide group of

fats by those of ordinary skill in the art in the field. Contrary to assertions made in the rejection, fats and waxes are distinct and would therefore not be unclear or indefinite. The Condensed Chemical Dictionary, Tenth Edition, (1981) provides definitions for both fat and wax:

fat. A glyceryl ester of higher fatty acids such as stearic and palmitic. Such esters and their mixtures are solids at room temperature and exhibit crystalline structure...There is no chemical difference between a fat and an oil, the only distinction being that fats are solid at room temperature and oils are liquid. The term "fat" usually refers to triglycerides specifically, whereas "lipid" is all-inclusive. See also lipid.

wax. A low-melting organic mixture or compound of high molecular weight, solid at room temperature and generally similar in composition to fats and oils except that it contains no glycerides. Some are hydrocarbons; others are esters of fatty acids and alcohols. They are classed among the lipids....

Thus, waxes can generally be distinguished from fats by the absence of glycerides. Note, that triglycerides are usually present in fats. Thus, Applicant contends that fat and wax are not redundant and would be distinguishable by those of ordinary skill in the art.

Applicant has amended claim 24, rendering the rejection of that claim moot.

Accordingly, Applicant respectfully requests the Examiner to reconsider and to withdraw the rejection of claims 2, 9, 11 and 19, 20, 22 and 24 under 35 U.S.C. §112, second paragraph.

2. REJECTION OF CLAIMS 1-14 AND 19-23 UNDER 35 U.S.C. §103(a)

Claims 1-14, 19-23 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Fielden (U.S. Pat. No. 5,660,860). As a basis for this rejection, the Office Action states:

Fielden discloses a composition containing the claimed materials (col. 9, lines 40-65 and col. 10, lines 25-34, col. 16, lines 61-70). Independent claim 1 differs from the reference in the length of the caplet. However, the diameter is given so that it is assumed that the length would be the same. Therefore, it would have been obvious to make a caplet containing the claimed ingredients in the particular size.

Independent claim 14 is to the method. Fielden discloses making a process of dry mixing all the ingredients, adding a lubricating material, i.e. aqueous alcohol to form a granulation solution, mixing and drying the granules, then compressing to make caplets in the diameter of 8.6 mm (col. 15, lines 60-67 and col. 16, lines 1-68). Claim 14 differs from the reference in the particular size of the caplet. However, no patentable distinction is seen in 8.6 mm and 7 mm at this time absent a showing of unexpected results using a slightly smaller size. Thus, it would have been obvious to make a caplet at about the claimed size.

RESPONSE

Applicant respectfully traverses this rejection. Applicant respectfully submits that the reference of record, Fielden, does not teach or suggest Applicant's inventive subject matter as a whole, as recited in the amended claims. Further, there is no

teaching or suggestion in this reference that would lead one of ordinary skill in the art to modify the reference to arrive at the subject of the amended claims with any expectation of success at the time the invention was made.

The U.S. Supreme Court in Graham v. John Deere Co., 148 U.S.P.Q. 459 (1966) held that non-obviousness was determined under § 103 by (1) determining the scope and content of the prior art; (2) ascertaining the differences between the prior art and the claims at issue; (3) resolving the level of ordinary skill in the art; and (4) inquiring as to any objective evidence of nonobviousness.

A. The present inventive subject matter

Independent claim 1 is presently directed to an encapsulated product comprising: at least one active ingredient, at least one compressible material and at least one lubricating material wherein the product is in the form of a caplet having a diameter from about 1 millimeter to about 7 millimeters and a length from about 1 millimeter to about 7 millimeters. Claims 2-13 are dependent therefrom adding further limitations.

Independent claim 14 is presently directed to a method for preparing an encapsulated product comprising the steps of: blending an active ingredient with a compressible material to form a compressible mixture; mixing the compressible mixture with

a lubricating material to form a final mixture; and compressing the final mixture into a caplet having a diameter from about 1 millimeter to about 7 millimeters and a length from about 1 millimeter to about 7 millimeters. Claims 19-23 are dependent therefrom adding further limitations.

B. The prior art

The Fielden patent (U.S. Pat. 5,660,860)discloses a water-dispersable tablet comprising acyclovir and a dispersing agent. The rejection cites the ingredients listed at col.9, lines 40-65 and col. 10, lines 25-34 as suggesting the claimed composition. Fielden discloses the ingredients acyclovir (5-90% wt); swellable clay (.25 to 50 % wt); binder (0-25 %wt); disintegrating agent(0-20 % wt); water-soluble filler (0-95% wt); water-insoluble filler (0-95% wt); wetting agent (0-5% wt); lubricant (0.1-5% wt); colours, flavours, sweeteners (0-10% wt); with an approximate tablet weight of 50-2000mg. The rejection also cites Fielden at col. 15, lines 60-67 and col.16, lines 1-68 as disclosing a process of dry mixing all the ingredients, adding a lubricating material, i.e. aqueous alcohol to form a granulation solution, mixing and drying the granules, then compressing the granules to make caplets of 8.6mm diameter.

**C. The differences between the claimed subject matter
and the prior art**

The differences between applicant's inventive subject matter and the cited reference is apparent from their independent and distinct disclosures and claim. Claim 1 is directed to an encapsulated product comprising at least one active ingredient, at least one compressible material, and at least one lubricating material wherein the product is in the form of a caplet having a diameter and length of 1 to about 7 millimeters. Fielden fails to teach or suggest an encapsulated product comprising the novel combinations of ingredients and sizes. This novel combination allows a surprisingly high amount of active ingredients or flavors and active ingredients to be entrapped by adsorption and compressed with high load into such a small encapsulated product without heat and moisture, a disadvantage of the prior art. See page 5, lines 9-16 of the Specification. Consequently, the encapsulated product containing the claimed material has a uniform active ingredient content and has mechanical processing advantages. See page 5, lines 1-6 of the Specification. The compressible of the novel products material may contain sugar or may be sugar-free depending on the whether the encapsulated product contains sugar or is sugar-free. See specific examples provided on page 7, lines 19-31. Thus, there is no teaching in

the Water-Dispersable Tablet of Fielden that suggests the presence of a high dose of active material in such a small product nor is there an appreciation of its attendant advantages, i.e. the elimination of the prior art problem, moisture and heat, as taught in the specification.

Furthermore, as the Examiner admits on the record, Fielden is silent with respect to the size of the caplet. As is stated above, the unique combination of materials and size of the caplet allows for a surprising amount of active materials to be incorporated into a small caplet without encountering the disadvantages of the prior art. The Examiner contends that the length of the tablet in Fielden would be assumed to be the same as the diameter given. However, Applicant respectfully submits that the assumption by the Examiner is improper because there is no indication in Fielden that this would be the case. In fact, Fielden is more concerned by the hardness of the tablets rather than the size of the tablets, as is evidenced in column 10, lines 18-19 when Fielden states "generally suitable compression weights and final tablet hardness will vary according to the size of tablet." (emphasis added) Thus, there is no indication or motivation in Fielden to attempt to limit the product size to that which is claimed.

Accordingly, independent claim 1 is not taught or suggested

by Fielden, thus, a prima facie case of obviousness has not been established. Dependent claims 2-13 which incorporate all the limitations of claim 1; therefore, must also be patentable over Fielden.

Claim 14 is directed to a method of preparing an encapsulated product comprising the steps of blending an active ingredient with a compressible material to form a compressible mixture; mixing said compressible mixture with a lubricating material to form a final mixture; and compressing the final mixture into a caplet having a diameter from about 1 to 7 millimeters and a length of about 1 to 7 millimeters. Fielden fails to teach or suggest a method that includes the step of compressing the final mixture into a caplet having a diameter from about 1 to 7 millimeters and a length of about 1 to 7 millimeters which aids in solving the prior art problem of having to use of heat and moisture. Thus, Fielden fails to teach or suggest the inventive subject matter of claim 14 as a whole with any expectation of success. Moreover, Fielden teaches away from the claimed inventive subject matter. The example methods covered by col. 15, lines 60-67 and col. 16, 1-68 as cited in the rejection of claims 19-23 require the use of solvents, such as 50% aqueous alcohol. See step (b) "Method of Preparation", col. 15, line 47 and step (b), Example 8, col. 16, line 41.

Conversely, the inventive subject matter of independent claim 14 requires no moisture or heat for its process to be operative. See page 4, lines 27-31 of the Specification.

Thus, Fielden fails to teach or suggest the inventive subject matter of independent claim 14 at the time the inventive subject matter was made. Accordingly, independent claim 14 and dependent claims 19-23, which contain all the limitations of claim 14, are not obvious over Fielden.

Applicant respectfully requests reconsideration and withdrawal of the 35 USC § 103 rejections of claims 1-14 and 19-23.

3. REJECTION OF CLAIM 24 UNDER 35 USC § 103(a)

The Office Action rejects claim 24 under 35 USC § 103(a) as allegedly being unpatentable over Cherukuri et al. (4,981,698).

The Office Action states:

Claim 24 further requires adding two encapsulated flavor ingredients to a food product. Cherukuri et al. disclose adding encapsulated sweeteners to chewing gums, confections, baked items, and pharmaceuticals (abstract and col. 20, lines 29-32). Nothing new or unobvious is seen in adding two encapsulated flavor ingredients to a food for their known functions especially since they are encapsulated and so one ingredient would not affect other encapsulated ingredients.

Applicant respectfully traverses this rejection. Applicant respectfully submits that the reference of record, Cherukuri et al. does not teach or suggest the subject matter as a whole of

independent claim 24 as recited in the claims. Further, there is no teaching or suggestion in this reference which would lead one of ordinary skill in the art to modify the reference to derive the subject matter as defined in claim 24.

The four-pronged test of Graham v. John Deere, is discussed above.

A. The present inventive subject matter

Claim 24 is presently directed to a method of delivering two flavor ingredients to an item selected from the group consisting of: a food item, a confectionery product, and a chewing gum product, said method comprising the steps of: a) incorporating into the item a first encapsulated product containing a first flavor; and b) incorporating into the item a second encapsulated product containing a second flavor.

B. The prior art

Cherukuri et al. discloses a delivery system for one or more sweeteners comprising a first high intensity sweetener encapsulated in a first core coating, and a second outer hydrophillic coating containing up to the solubility limit of the second coating of a second sweetener. See Cherukuri et al. at abstract. Cherukuri et al. also claims a method for preparing a sweetener delivery system comprising: a) entrapping a sweetener in a polyvinyl acetate coating comprising the steps of melting and

blending the polyvinyl acetate with an emulsifier and dispersing the sweetener uniformly therein, cooling the mixture at ambient temperature while continuing to mix; b) grinding the resultant mixture to the desired particle size; c) coating the resulting particles with a second coating material by a fluidized bed-type process; and d) recovering the final plural coated particles. See Cherukuri et al. at claim 27.

**C. The differences between the claimed subject matter
and the prior art**

The Office Action cites the abstract and col.20, lines 29-32 which are steps (b) and (c) of claim 27 of Cherukuri et al. as rendering claim 24 obvious. However, the cited reference fails to teach or suggest a method of delivering two flavor ingredients to a food item by separately encapsulating a first flavor which is incorporated into the food item and then separately delivering a second flavor which is encapsulated into the food item with both flavors being encapsulated. Cherukuri et al. utilizes a distinct method by which a structurally distinct product in the form of a sweetener is introduced.

In Cherukuri et al., a first sweetener is encapsulated in a first core coating with the resultant product being coated with a second hydrophillic coating containing up to the solubility limit of the second coating of the second sweetener. See Cherukuri et

al. at abstract. The delivery system of Cherukuri et al. requires liquid mixing of the core material by melting at 85°C. See col. 9, lines 14-21 and col. 9, lines 36-41. Conversely, the method of claim 24, which incorporates the entire inventive subject matter, requires no heat or moisture which is the prior art problem which has been overcome. See page 10, lines 8-15 of the Specification. Thus, the method of Cherukuri teaches away from the inventive subject matter.

Moreover, high concentrations of flavorings may be incorporated in the final product which is a surprising result. See page 10, lines 8-15 of the Specification. The method of claim 24 simply uses an encapsulated first active which is incorporated into the food item followed by a second encapsulated active which is then incorporated into the food item. Lastly, Applicant points out that 35 USC § 103(a) states:

..."patentability shall not be negated by the manner in which the invention was made."

Thus, absent some teaching of the prior art or knowledge of those of ordinary skill in the art, a mere observation of the apparent simplicity of the inventive subject matter is grossly insufficient to establish a prima facie case of obviousness under 35 USC § 103(a).

Thus, there is no teaching or suggestion of the inventive subject matter of claim 24 nor any suggestion to modify the

teachings of Cherukuri et al. to arrive at claim 24.

CONCLUSION

In view of the foregoing, applicant respectfully requests the Examiner to reconsider and withdraw the rejection of the claims and to allow all of the claims pending in this application.

If the Examiner has any questions or wishes to discuss this matter, the Examiner is welcomed to telephone the undersigned attorney.

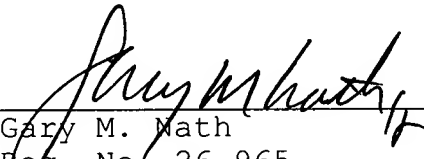
Respectfully submitted,

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